Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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DATE: July 13, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Brookstone Pharmaceuticals Recall

SUGGESTED ACTION: **Unclassified Recall; Brookstone Pharmaceuticals' Concentrated Acetaminophen Drops; Information provided in case of consumer inquries.**

From the information provided by FDA, the product being recalled has been distributed in the State of Indiana. Brookstone has distributed 344 bottles nationally and has donated 5301 bottles to charity for international distribution. Over dosage of acetaminophen may result in liver toxicity, kidney damage, and blood disorders. FDA is aware of several medication error reports that document life-threatening or fatal adverse events in children less than three years of age, due to confusion associated with the concentrated versus regular strength acetaminophen liquid.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Brookstone Pharmaceuticals Issues a Voluntary Recall of All Lots of Brookstone Pharmaceuticals' Concentrated Acetaminophen Drops

FOR IMMEDIATE RELEASE – July 13, 2009 – Brookstone Pharmaceuticals, LLC, Alpharetta, GA has initiated a nationwide voluntary recall of all lots of Concentrated Acetaminophen Drops

(NDC#42192-504-16) in 16 ounce (473 ml) bulk containers. This 16oz container is comparable to the size generally used to package regular strength acetaminophen liquid preparations. This aspect of the product coupled with the absence of an integrated dosage delivery device is a contributing factor to possible dosing errors, especially inadvertent overdosing. Brookstone has distributed 344 bottles nationally and has donated 5301 bottles to charity for international distribution.

Over dosage of acetaminophen may result in liver toxicity, kidney damage, and blood disorders. FDA is aware of several medication error reports that document life-threatening or fatal adverse events in children less than three years of age, due to confusion associated with the concentrated versus regular strength acetaminophen liquid. Also, in a recent FDA advisory panel, it was recommended that one of the two strengths of acetaminophen should be removed from the market due to possible confusion which could result in overdosing.

Brookstone's concentrated acetaminophen contains acetaminophen 80 mg/0.8 mL. Regular strength acetaminophen elixir contains 160 mg/5 ml. The firm is recalling its product to the consumer level as a cautionary measure to minimize any confusion and potential risk to patients from dosing errors.

Brookstone Pharmaceuticals has notified customers that it has voluntarily stopped manufacturing and shipping Concentrated Acetaminophen Drops in bulk containers and has also advised customers (wholesalers and hospitals) to quarantine and hold the product for return to Brookstone Pharmaceuticals for a full refund. Customers with questions about the recall may contact Brookstone Pharmaceuticals, LLC at 1-800-541-4802, option 2. Brookstone has not received any adverse events associated with this product but due to recent advisory panel concerns, Brookstone has taken voluntary action.

The recalled drops were manufactured by Pharmaceutical Associates, Inc. This recall is being conducted with the knowledge of the Food and Drug Administration.

Customers who have this product in their possession should stop using it immediately. Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088 or by fax at 1-800-FDA-0178 or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

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